

Establishment Inspection Report

Medrad Inc dba Bayer R&I
Indianola, PA 15051-9759

FEI: 2520313

EI Start: 08/08/2013

EI End: 08/12/2013

SUMMARY OF FINDINGS

Inspection of this manufacturer of class II devices was conducted as a routine FY13 work plan assignment (FACTS # 8690859). This was a level II QSIT inspection conducted per CP 7382.845 and FDA's *Guide to Inspection of Quality Systems*. The previous FDA inspection of this site was conducted in May 2012 as F/U to firm initiated recall of non-conforming *Continuum* MR infusion pumps, that limited inspection was classified NAI.

Upon arrival we presented credentials and a NOI to Mr. William E. Bullis, VP Sterile Disposables Manufacturing. Others participating substantially in the inspection included Mr. Govardhan Singh, Engineering Manager Operations QA, Tim Anderson, Head of Quality R&I; Julia Mitchell, Director Commercial Quality R&I. Mr. Sam Liang, CEO of Medrad, Inc. continues to be the individual ultimately responsible for operations at Medrad facilities.

Inspection coverage included review of the Management Controls, Design Controls, CAPA and Process Control subsystems as applicable to the currently inspected site. This inspection was the third and final EI of multiple sequential audits of Medrad's three Pittsburgh area producing facilities. The current inspection revealed that this site continues to produce lower volume sterile disposables including syringe assemblies and administration sets. Processing operations are largely unchanged from those described in previous EIRs, with some new capital equipment and additional automation cells implemented. This site shares a QMS and MIS with the other recently inspected Medrad / Bayer R&I sites. Current organizational structure is documented in the August 2013 EIR of the Heilman Center plant.

Review of Management Control activities at this and other sister facilities revealed no deficiencies.

Design Control procedures were reviewed, along with implementation of same on the firm's recently commercialized *Arterion* CV injector. We reviewed elements of the Design History File including project plans, System Requirement Specifications, Risk Management File, V&B plans and selected test protocols and reports, Design Review documentation, Software requirement specifications, software V&V activity documentation, and issue tracker / management system used by the firm (b) (4). We also assessed configuration management practices during the development cycle. No deficiencies were noted with respect to design controls.

We reviewed firm's CAPA related activities, including trending and analysis of quality system information, presentation and reporting of same, nonconforming material handling, disposition and investigation practices, complaint processing and adverse event reporting practices, and management of formal CARs. We observed no significant deficiencies relative to the CAPA subsystem.

Our assessment of this site's Production and Process Control subsystem included a review of qualification activities for a recently installed (b) (4) and associated control and in-line inspection systems, review of environmental monitoring practices including handling of alert and action level events for bioburden monitoring, and endotoxin testing processes. We reviewed the firm's practices relating to routine re-validation of sterilization dose. No deficiencies were observed relative to Production and Process Controls.

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During final close-out we were joined by Mr. Bullis; Jennifer Farr, VP Quality Bayer HealthCare LLC (Tarrytown); Tim Anderson; Julia Mitchell, et al. In the absence of adverse findings final discussions were relatively brief. WE discussed a minor concern relating to the apparent contribution of human error to process deficiency related non-conformances and the potential relationship of same to firm's utilization of temporary employees, while acknowledging the apparent absence of any employee training related deficiencies. We thanked the firm and closed the inspection, advising collected management that they should consider the inspections of the sister facilities closed as well.

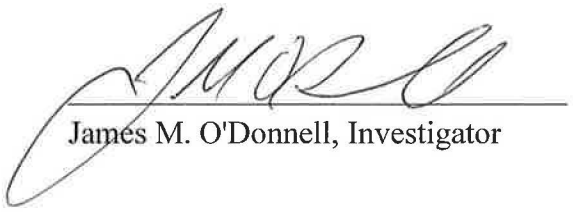

ADMINISTRATIVE DATA

Inspected firm: Medrad Inc dba Bayer R&I
Location: 1 Medrad Dr
Indianola, PA 15051-9759
Phone: 412-767-2400
FAX: 412-767-2885
Mailing address: 1 Medrad Dr
Indianola, PA 15051-9759
Dates of inspection: 8/8/2013, 8/9/2013, 8/12/2013
Days in the facility: 3
Participants: James M. O'Donnell, Investigator
Dennis Hock, Investigator

This was a team inspection conducted by Investigators Jake O'Donnell and Dennis Hock. Mr. O'Donnell wrote this EIR.

ATTACHMENTS

- 1.) FDA 482 Notice of Inspection


James M. O'Donnell, Investigator
Dennis Hock, Investigator